MAY - 7 2001

510(k) Summary

K010813

1. Name/Address of Submitter: NeoRad AS
   Parkveien 55
   0256 Oslo
   Norway

2. Contact Person: Charles H. Kyper
   Kyper & Associates
   (919) 960-0049

3. Date Summary Prepared: March 15, 2001

4. Device Name: SimpliCT™

5. Predicate Devices: Elscint Inc. CT Scope (K974344)
   UltraGuide Ltd. UltraGuide CT-Guide 1010 (K002258)
   Marconi Medical System PinPoint (K974513)
   Ferguson Medical TargoBeam (K970819)
   LAP of America L.C. PatPos [510(k) number unknown]

6. Device Description and Intended Use:

   SimpliCT™ is an optical guidance device indicated for use with a computed tomography x-ray system to facilitate CT-guided punctures with straight needles.

   SimpliCT™ consists of a movable Laser Unit mounted on a horizontal or vertical rail. The Laser Unit is shielded by a plastic housing and contains a battery power supply, electronics, switches, display unit, and two lasers: (1) alignment laser for positioning of the device relatively to the CT-table and (2) an adjustable pointing laser for needle guidance. Through the auto-calibration system, SimpliCT™ always assures that the desired point and angle are correctly achieved. It is a stand-alone device which is neither physically connected to the CT-unit nor to the needle.

7. Brief Description of Nonclinical and Clinical Testing:

   The specifications and test procedures for electrical safety and software verification/validation reference appropriate international standards. All product specifications were met.

   Clinical study information was submitted.

8. Conclusions Drawn:

The indications for use are consistent with those for legally marketed optical guidance devices used in conjunction with CT x-ray systems. Differences in technological characteristics do not raise new issues of safety or effectiveness and are addressed in the 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2001

NeoRad AS
c/o Charles H. Kyper
Kyper & Associates
103 Nolan La.
Chapel Hill, NC 27516

Re: K010813
SimpliCT™
Dated: March 16, 2001
Received: March 19, 2001
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. Kyper:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indication for Use

510(k) Number (if known): K010813

Device name: SimpliCT™

Indication for Use: The SimpliCT™ is an optical guidance device indicated for use with a computed tomography x-ray system (CT) to facilitate CT-guided punctures with straight needles.

Concurrence of CDRH Office of Device Evaluation

Prescription Use ✓ OR Over-the counter Use _____
(per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010813